1,174,814

PATENT SPECIFICATION

DRAWINGS ATTACHED

1,174,814

Inventor: ROLF DIETER GRUNERT

Date of Application (No. 6579/67) and filing Complete Specification: 10 Feb., 1967.

Application made in Germany (No. G45989 IXd/30d) on 10 Feb., 1966.

Application made in Germany (No. G47259 IXd/30d) on 23 June, 1966.

Complete Specification Published: 17 Dec., 1969.

Index at acceptance:—A5 RBX15; H2 J(2C, 12C, 12H2)

International Classification:—A 61 f 1/00

COMPLETE SPECIFICATION

Device for Occlusion and Release of Natural or Artificially Constructed Ducts in the Human or Animal Body

I, ROLF DIETER GRUNERT, a citizen of Germany, of 20 Leimenstrasse, 645 Hanau, Germany, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to medical prosthetic devices generally and more particularly to a device for the occlusion and release of natural or artificially constructed ducts in the human or animal body being operated either manually or by facilities located outside of the body and having an envelope of material compatible with the environment of the body to permit its implantation therein. Briefly such a device can be termed an artificial sphincter.

It has been made feasible to implant foreign material within the human or animal body, which may be incorporated at least for many years or even permanently. Foreign material which apparently can be implanted within living beings without severe reactions include latex rubber, stainless steel, "Teflon," "Dacron" (Registered Trade Marks), nylon and especially a special type of silicone rubber. Appliances which at present have been implanted successfully within the human or animal body include artificial blood vessels, artificial heart valves and especially cardiac pacemakers (U.S. patent No. 3,057,356) which excite the heart in case the cardiac conduction system has failed.

An object of this invention is to provide implantable prosthetic devices, which are suitable for occluding and releasing natural or artificially constructed ducts in the human or animal body. These devices should be of such a disposition, that they can be readily operated from the outside, in case of the human body by the persons in question themselves.

The demand for such a device arises, whenever natural sphincters, occurring for example at the cardia, the pylorus, within the bile ducts and at the termination of the intestinal and urinary tracts, fail or have been removed operatively. It is conceivable, that an artificial sphincter might also be useful for the occlusion or release of intestinal or vascular ducts within the body, where natural sphincters do not occur, for example at the termination of a residual small bowel, when large parts of the small intestine have been removed operatively, or, in the case of blood vessels for example in portal hypertension for the compression of esophageal varices. Attempts at operative reconstruction of sphincters have largely been unsuccessful and to the best of my knowledge this is the first attempt to solve the problem by means of implantable prosthetic devices.

According to the invention there is provided a device for the occlusion and release of a natural or artificially constructed duct in the human or animal body, wherein a pneumatically, hydraulically, mechanically or electrically operable occluding body is directly or indirectly connected with operating means for causing movement of said body to close or release said duct, said means being capable of being operated either manually or by remote control means located outside the body, and wherein the device has an envelope of material which is compatible with the environment of the body whereby the device can be wholly implanted within the body.

The pneumatically or hydraulically operable occluding body may consist of at least one inflatable occluding part, which is inflated by a filling agent, fed through a connecting tube.

The occluding parts may be connected through the connecting tube with a container of variable volume, which is implanted under the skin, said container having an arresting mechanism for holding the occluding parts in an inflated condition.

[Price 4s. 6d.]

In still another form of construction of the invention, a pump may be arranged between the occluding body and a container, occluding and releasing function being obtained by the action of the pump.

The occluding body may consist of an inflatable ring or of two inflatable bellows, which can be connected with each other on the ends, allowing the occluding parts to be put around the duct to be occluded without injury to the wall of the duct or its blood supply.

In another form of construction, the occluding body may function like a hose clamp, consisting of one fixed and one mobile part, the latter being moved by a cable, a rotating shaft or by a bellows extension, this form of construction being operated either manually or by other drive means.

In still another form of construction, the occluding body may directly or indirectly be operated by a magnet or by an electromagnet.

The occluding function may also be effected by a sling, which is occluded by a cable or some other mechanical device and released by the action of a spring.

In another form of construction of the invention, a motor and switches may be implanted within the body which may be operated from the outside. A receiver, which is controllable by an externally located transmitter may also be implanted within the body for motor control.

The source of energy for the motor may be implanted or the energy may be transmitted from outside of the body by induction. The energy may be fed on two different resonant circuits for operation of the drive means in two different directions.

The energy for the new artificial organ may, by means of induction, be fed on rechargeable batteries which, in turn, give off the energy to the drive means on actuating a remote control.

In still another form of construction, the total energy for the operation of any of the described constructions may be obtained from a permanent magnet or an electromagnet, acting upon a magnetic material or another magnet or electromagnet implanted within the body.

The occluding parts in any of the described constructions may be lined by sponge rubber, foamed plastics or formed with soft riflings or teeth of rubber or plastics to ensure fixation and to avoid sliding on the duct to be occluded.

Drive means and the components for the energy supply of the drive means may be cast into a hard epoxy resin which may have an envelope of silicone rubber or of another compound which is compatible with the environment of the body. All components are miniaturized so that the physical configuration provides minimum size and weight to make feasible total implantation within the body.

It will be readily apparent to those skilled in the art, that the present invention provides a medical prosthetic device which, in effect, represents an artificial sphincter. The new artificial organ may be implanted within the human or animal body in its entirety to effectively control the passage through blood vessels, bile ducts and especially the urinary tract and the intestinal canal, whenever natural sphincter mechanisms fail or have been removed, or whenever the necessity arises to create new sphincter mechanisms within the human or animal body. The advantage over attempts at sphincter replacement by plastic methods of repair or transplantation of muscles lies in the ready availability of the artificial material and in the fact, that attempts at sphincter replacement by autogeneous material have largely been unsuccessful, especially in adults.

Certain embodiments and details of construction of the invention are illustrated in the accompanying drawings in which:

Fig. 1 illustrates an embodiment of the invention in which pneumatic or hydraulic means are provided for operation of the occluding body.

Fig. 2 illustrates a pneumatically or hydraulically operable embodiment of the invention with a pump.

Fig. 3 illustrates a mechanically operable occluding body with a cable in a flexible steel conduit.

Fig. 4 shows a circuit diagram with implanted switches for control of the driving means.

Fig. 5 shows a circuit diagram for the inductive feed of energy upon two different resonant circuits for operation of the drive means in two different directions.

Fig. 6 shows means for the control of the implanted components for the energy supply of the drive means and means for the energy supply of the artificial organ.

Referring now in detail to the illustrative embodiments. Fig. 1 shows the occluding body 1, which consists of two occluding parts 2 which have a special lining 3, being directed towards the pathway to be occluded in order to ensure a reliable occlusion. The occluding parts 2 consist of latex rubber or rubber-like plastics, e.g. silicone rubber. Their volume is variable. The occluding body 1 is connected with a bellows-like container through a tube 4. Within the container 5 a pressure spring 6 is arranged, which tends to enlarge the container towards its greatest volume. On actuation of a push-button 7 the liquid or gas can be pressed from the container 5 through the tube 4 into the occluding body 1, especially into the occluding parts 2 which are caused to inflate. To maintain the occlusion of the natural or artificially constructed ducts, facilities are provided within the container 5, which arrest the container in a compressed state. The push-button 7 may be located under the skin

in such a way that the desired actuation is easily possible and an undesired actuation is not possible. The device is provided with an arresting mechanism comprising a plate 8 and plugs 9 fixedly connected to the push-button 7. Each of the plugs 9 is formed with a notch which can engage in a respective aperture in the plate 8 when the push-button 7 is pushed in to expel the liquid or gas from the container 5 to inflate the occluding parts 2. The plate 8 is formed in two parts held together by elastic means, such as a rubber band, and a wedge-shaped depression is formed in the centre of the plate. The end of the stem of the push-button 7 can enter the depression and further pressure on the push-button causes the two halves of the plate 8 to be moved apart to release the plugs 9 from the holes whereby the spring 6 restores the container to the position shown in Fig. 1 and the gas or liquid is withdrawn from the occluding parts 2 to release the duct.

In order to enable the device shown in Fig. 1 to be implantable into the body, it is covered with an envelope of material which is compatible with the environment of the body, such envelope not being shown in the drawing.

In Fig. 2 a peristaltic pumping arrangement 10 is located between the variable volume container 5 and the occluding body 1, said pumping arrangement consisting of a motor 11 and a horse-shoe shaped component 12, on which a tube is squeezed by rollers 13 such that the filling agent is transferred from the container 5 into the occluding body 1 or vice versa. The motor 11 has two connections 14 for the electrical feed from a supply of electrical energy or a receiver therefor (not shown). Again the whole of the device including the energy supply or receiver has an envelope of material which is compatible with the environment of the body so tht the whole of the device can be implanted in the body.

Fig. 3 illustrates a mechanically operable occluding body, consisting of a U-shaped fixed part 15 and a mobile and guided part 16. The mobile part 16 is connected through a "Bowden" (Registered Trade Mark) cable 18 with drive means 19 consisting of a motor 20, which, through a worm gear shaft 21, acts on a pinion 22. This pinion 22 is arranged on a shaft 23 on which the "Bowden" cable 24 can be wound up, the free end of the cable being fixed to the mobile part 16. Thereby it is possible to move the mobile part 16 against a pressure spring 25 and so to release the duct. Those parts of the occluding body, which are directed towards the duct to be occluded may be provided by a lining 17. Again the whole of the device including the energy supply or receiver has an envelope of material which is compatible with the environment of the body so that the whole of the device can be implanted in the body.

Fig. 4 illustrates a circuit diagram for the operation of the motor 19 of Fig. 3, the device including a miniaturized motor and an energy source 26, all for implantation in the body. One terminal of the energy source 26 is electrically connected with both a first contact of a first pole of a double pole magnetic change-over switch 28 and one contact of a simple magnetic switch 27 and the other terminal of the energy source is connected with a second contact of first pole of the magnetic changeover switch and with a first contact of the second pole of the magnetic changeover switch, the second contact of the second pole of the magnetic changeover switch being connected with the second contact of the magnetic switch 27. On actuation of the magnetic switch 27 the motor 19 is operated in one direction and on actuation of the switch 28 in the other, the switches being connected with the energy source 26 and the motor 19 in such a way, that short circuit cannot occur. The magnetic switches may be actuated from the outside by a permanent magnet. However, the switches 27 and 28 may be replaced by implanted relays and can then be operated by energy, which has been fed in inductively.

Fig. 5 shows a circuit diagram, in which two different resonant circuits 30 and 31 are implanted within the body together with the device. One terminal of each resonant circuit is connected with diodes 32 and 33 respectively, the diode 32 being electrically connected with both the emitter of a transistor 35 and the base of another transistor 35. The anode of the other diode 33 is electrically connected with the collector of the latter transistor 35 the emitter of which is connected with one terminal of the motor 19. The collector of the first mentioned transistor 35 is connected with the other terminal of the motor which terminal is also connected with the other terminals of the resonant circuits. After rectification of high frequency by diodes 32 and 33, the drive means 19 is operated in one or the other direction, depending on which of the two resonant circuits is syntonized. A condensor 34 is connected in parallel with the drive means 19 for smoothing the rectified high frequency energy and the transistors 35 serve for preventing the flow of current into one resonant circuit when the other is activated.

Fig. 6 illustrates facilities for remote control and energy supply of the implanted electronic device, 29 designating two different permanent magnets and 36, 37 and 38 high frequency energy source, transmitting coil and variable condensor of a sender.

WHAT I CLAIM IS:—

1. A device for the occlusion and release of a natural or artificially constructed duct in the human or animal body wherein a pneumatically, hydraulically, mechanically or electrically operable occluding body is directly or indirectly connected with operating means for

causing movement of said body to close or release said duct, said means being capable of being operated either manually or by remote control means located outside the body, and wherein the device has an envelope of material which is compatible with the environment of the body whereby the device can be wholly implanted within the body.

2. A device as claimed in Claim 1, wherein said occluding body consists of one or several occluding parts to which a filling agent can be fed through a connecting tube from a container with variable volume, either manually under the control of an arresting mechanism or by a pumping arrangement operable by remote control.

3. A device as claimed in Claim 1, wherein the means for operating the occluding bodies is operable mechanically by means of a cable.

4. A device as claimed in claim 1 or Claim 3, wherein the occluding body consists of a sling, which may be tightened by a cable and loosened by the action of a spring.

5. A device as claimed in claim 1 or 2, wherein the occluding body is directly or indirectly connected with a miniaturized drive means, said drive means consisting of an energy source one terminal of which is electrically connected with both a first contact of a first pole of a double pole magnetic changeover switch and one contact of a simple magnetic switch and the other terminal of which is connected with a second contact of the first pole of said magnetic changeover switch and a first pole of said magnetic changeover switch and a first contact of the second pole of the magnetic changeover switch, the second contact of the second pole of the magnetic changeover switch being connected with the second contact of said simple magnetic switch, by which circuit connections a reversal of current direction may be obtained without short circuit, when the single magnetic switch or both the changeover magnetic switches are actuated by a magnet, the turning contacts of said changeover switches finally being connected with mechanical drive means.

6. A device as claimed in Claim 7, wherein the magnetic switches are replaced by relays operable by energy inductively fed thereto.

7. A device as claimed in Claim 1 or 2, wherein the occluding body is directly or indirectly connected with a miniaturized drive means, said drive means consisting of two resonant circuits one terminal of each of which is connected with diodes one of the diodes being electrically connected with both the emitter of one transistor and the base of another transistor, the anode of the other diode being electrically connected with the collector of the latter transistor, the emitter of which is connected with one terminal of a motor, the base of the first mentioned transistor being connected with the other contact of the motor, this same contact being also connected with both of the other terminals of the resonant circuits, and a condensor being connected in parallel with the motor.

8. A device as claimed in any one of the foregoing Claims, wherein those surfaces of the occluding body which are directed towards the duct to be occluded, are lined by sponge rubber, foamed plastics or formed with soft riflings or teeth of rubber or plastics to ensure fixation and to avoid sliding of the duct to be occluded.

9. A device for occluding and releasing a duct within the human or animal body substantially as hereinbefore described with reference to any one of Figures 1 to 6 of the accompanying drawings.

TREGEAR, THIEMANN & BLEACH,
Chartered Patent Agents,
Melbourne House, Aldwych,
London, W.C.2.
Agent for the Applicant.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa. 1969.
Published by the Patent Office, 25 Southampton Buildings, London, W.C.2, from which copies may be obtained.

1174814 COMPLETE SPECIFICATION
3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

Fig. 1

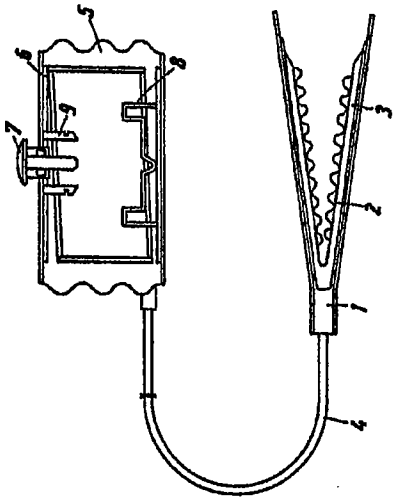
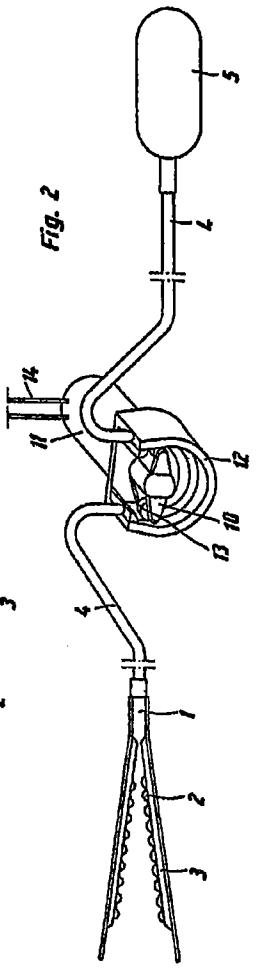


Fig. 2



1174814 COMPLETE SPECIFICATION
3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 2

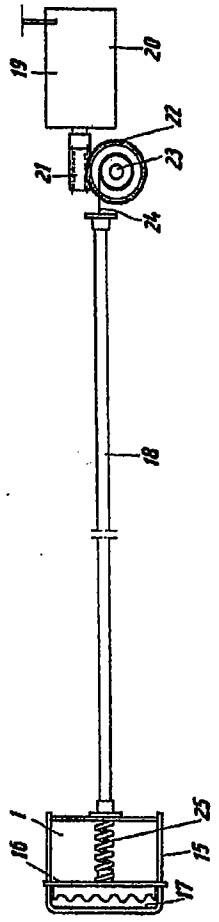


Fig. 3

1174814 COMPLETE SPECIFICATION
3 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 3

Fig. 4

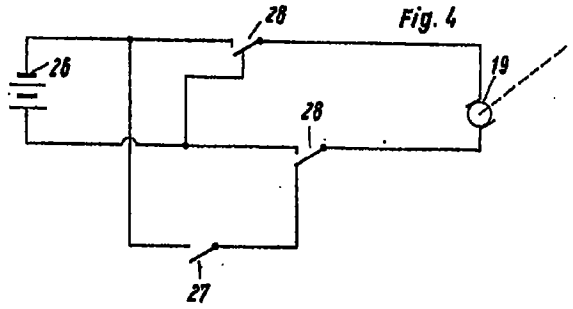


Fig. 5

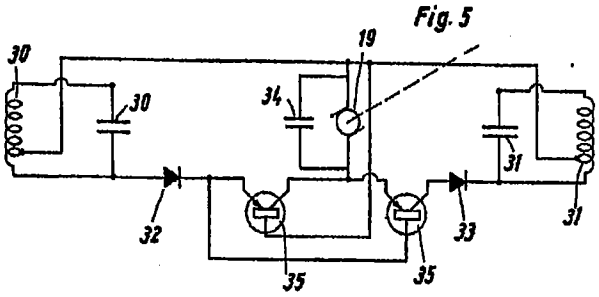


Fig. 6